

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF OKLAHOMA**

(1) ABBVIE INC.;  
(2) ALLERGAN, INC.;  
(3) DURATA THERAPEUTICS, INC.;  
(4) ABBVIE PRODUCTS LLC;  
(5) PHARMACYCLICS LLC; and  
(6) ALLERGAN SALES, LLC,

*Plaintiffs,*

v.

(1) GENTNER DRUMMOND, in his  
official capacity as Attorney General of the  
State of Oklahoma,

*Defendant.*

Case No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively “AbbVie”), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Oklahoma Attorney General, challenging the applicability and constitutionality of Oklahoma’s recently enacted H.B. 2048. In support, AbbVie alleges as follows:

**PRELIMINARY STATEMENT**

1. AbbVie brings this lawsuit to challenge the constitutionality of H.B. 2048—a recently enacted Oklahoma law that requires AbbVie to transfer its pharmaceutical products to certain commercial pharmacies at substantially discounted prices on pain of civil and criminal penalties. In so doing, Oklahoma’s statute violates the Supremacy

Clause by impermissibly changing the terms of a federal drug-pricing regime—the federal 340B program—and significantly increasing the cost of participation in that regime. In addition, H.B. 2048 effects an unconstitutional taking in violation of the Takings Clause of the Fifth Amendment. It is also unconstitutionally vague.

2. H.B. 2048 arises out of a long-running dispute about the requirements that the federal 340B program places upon drug manufacturers. In short, the federal 340B statute, 42 U.S.C. § 256b, establishes a comprehensive program that requires pharmaceutical manufacturers to offer their drugs at statutorily set and significantly reduced prices to a list of fifteen specifically enumerated types of healthcare providers known as “covered entities.” Opting into the 340B program and making these offers of drugs at the significantly reduced prices is required for manufacturers who want to participate in federal Medicaid and Medicare programs. *See* 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

3. Under the 340B statute, manufacturers are required only to “offer” their drugs to covered entities at the 340B price—not “sell” them *unconditionally*. 42 U.S.C. § 256b(a)(1). That is, the 340B statute requires only that manufacturers make an offer at a particular price to a particular set of covered entities but preserves the liberty of manufacturers to insist upon other non-price terms. And commercial pharmacies, like Walgreens and CVS, are not among the 340B statute’s list of entities entitled to an “offer” of the 340B price.

4. The federal statute grants the Secretary of the U.S. Department of Health and Human Services (“HHS”) *exclusive* authority to enforce its provisions. *See* 42 U.S.C.

§ 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in Medicaid and Medicare. Nor do states or other third parties have any authority to enforce the federal statute’s requirements. The Supreme Court has held that third-party enforcement “would undermine the agency’s efforts to administer” the 340B program and other related federal programs “harmoniously and uniformly.” *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 119-20 (2011).

5. Further, because forcing manufacturers to transfer their drugs at discounted prices to covered entities would raise serious constitutional concerns, Congress did not mandate participation in the 340B program outright and instead tied it to a voluntary choice: participation in Medicaid and Medicare. And to further incentivize manufacturer participation in 340B—*i.e.*, to prevent the cost of participation from becoming too high—Congress carefully limited the program and adopted certain safeguards to ensure that manufacturers’ discounted drugs would be used to help needy patients, rather than become a buy-low, sell-high scheme for commercial entities. For example, in a statutory provision designed to prevent “diversion,” Congress prohibited covered entities from transferring manufacturers’ reduced-price drugs to anyone other than the entity’s own patients. *See* 42 U.S.C. § 256b(a)(5)(B). In effect, that provision prohibits other commercial entities from either participating in the 340B program or profiting from the sale of manufacturers’ drugs at the 340B discounted price.

6. Nevertheless, over the last decade covered entities have entered into novel contractual arrangements with commercial pharmacies (called “contract pharmacies”) that

have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

7. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States. They solely exist in the 340B context, where they are unauthorized by statute. AbbVie is involved in no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

8. In response to these abuses—and because Congress left room for manufacturers to impose reasonable conditions on their 340B offers—manufacturers (including AbbVie) have exercised that right by implementing policies that effectively condition the sale or transfer of drugs at 340B-discounted prices to covered entities and their affiliated contract pharmacies. AbbVie's policy reflects the reality that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the

covered entities. It does not compel unconditional sales, nor does it require manufacturers to transfer 340B-discounted drugs wherever and to whomever a covered entity demands. And it certainly does not require manufacturers to subsidize commercial pharmacy *profits* under the guise of 340B compliance.

9. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and HHS and, in early 2023, the U.S. Court of Appeals for the Third Circuit confirmed that the manufacturers' policies are lawful and permitted under federal law. Again, Congress required manufacturers to *offer* their covered outpatient drugs at discounted prices in return for participating in Medicaid and Medicare; it did not impose any additional obligation on manufacturers to provide their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts. Commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B-discounted price. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023).

10. In May 2024, the U.S. Court of Appeals for the D.C. Circuit agreed with the Third Circuit's conclusion, holding that because "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," the statute gives manufacturers freedom "to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). And because conditions such as limiting delivery to "a single contract pharmacy designated by the covered entity" in no way impair a manufacturer's offer to sell drugs at

the 340B-discounted price, the restrictions fall within the ambit of freedom manufacturers enjoy under the federal 340B statute. *Id.* at 462-64.

11. Numerous states participated in the Third Circuit and D.C. Circuit cases as *amici curiae*, on the losing side. After that loss, many states turned to their own legislatures to propose and implement legislation to reach their desired 340B outcomes and attempt to impose requirements under the federal 340B statute that Congress chose not to impose. Oklahoma’s H.B. 2048 is an example of one such piece of legislation.

12. In particular, H.B. 2048 not only eliminates manufacturers’ federally preserved ability to impose reasonable conditions on their 340B offers—it imposes new conditions on Medicare and Medicaid participation that Congress never authorized. *See Novartis*, 102 F.4th at 460 (“[W]e think that this silence *preserves*—rather than abrogates—the ability of sellers to impose at least some delivery conditions.” (emphasis added)). Among other things, H.B. 2048 prohibits manufacturers from limiting the “acquisition” of 340B discounted drugs by for-profit pharmacies contracted with covered entities. H.B. 2048 § 4(A). Oklahoma’s law effectively transfers to covered entities ***and commercial pharmacies*** unfettered authority to demand manufacturers’ property at significantly reduced prices for the benefit of private parties.

13. To be clear, the harm AbbVie challenges in this action arises not from the federal 340B program or the replenishment model itself, but from H.B. 2048’s prohibition on manufacturers’ ability to condition their federal 340B offers. Even in the absence of the replenishment model, Oklahoma’s law would injure manufacturers like AbbVie because H.B. 2048 would still compel AbbVie to transfer its drugs at confiscatory prices

under conditions AbbVie would not agree to and beyond what the federal statute requires as a matter of Medicare and Medicaid participation. AbbVie’s injury stems from the state-law expansion of AbbVie’s obligations—not from the design or administration of the 340B program.

14. This state-imposed harm—compelling manufacturers to transfer their drugs at discounted prices on terms not required by federal law and to which AbbVie would not agree—cannot stand because it violates the United States Constitution. H.B. 2048 should be enjoined.

15. **First**, H.B. 2048 is preempted by federal law under the Supremacy Clause. The doctrine of federal preemption requires that “any state law, however clearly within a State’s acknowledged power, which interferes with or is contrary to federal law, must yield.” *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 108 (1992). Oklahoma’s H.B. 2048 must yield. By seeking to change the requirements of when and to which entities manufacturers must offer drugs at a discounted price as a condition of participating in federal Medicaid, H.B. 2048 unlawfully modifies the requirements of the federal 340B program. H.B. 2048 likewise obstructs the 340B statute’s objectives by imposing obligations on drug manufacturers that conflict with the actual federal requirements, thereby raising the costs of Medicaid participation above those set by Congress and deterring manufacturers from participating at all. And H.B. 2048 impermissibly injects state officials armed with state-law penalties (including criminal penalties) into what Congress intended to be an exclusively federal compliance scheme.

16. **Second**, H.B. 2048 is an impermissible taking under the Fifth Amendment. Neither the federal government nor the States have any authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005). Oklahoma’s law does just that. It requires drug manufacturers like AbbVie to transfer their property at steeply discounted prices to other private entities if those entities have third-party contracts that purport to allow them to access AbbVie’s drugs at those discounted prices. And H.B. 2048’s text makes clear that it seeks to regulate “acquisition” of said drugs at the discounted 340B price. *See* H.B. 2048 § 4(A). Oklahoma has no authority to take AbbVie’s private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide 340B-priced drugs to contract pharmacies at the request of covered entities, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep’t of Agric.*, 576 U.S. 350, 370 (2015) (holding government’s confiscation of portion of farmers’ raisin crop for charitable or other purpose without just compensation was a *per se* taking).

17. **Third**, H.B. 2048 violates AbbVie’s due process rights because it is impermissibly vague. *See Wyo. Gun Owners v. Gray*, 83 F.4th 1224, 1233 (10th Cir. 2023). The statute contains broad, open-ended, and ambiguous provisions—provisions that fail to place AbbVie on notice of what is prohibited, and that invite arbitrary enforcement. For example, H.B. 2048 bars manufacturers from “interfere[ing] with a pharmacy contracted with a 340B entity” without providing any elaboration or guidance. H.B. 2048 § 4(B).

Worse, “340B entity” is itself defined to include contract pharmacies—so the law somehow prohibits AbbVie from “interfering” with pharmacies contracted with other contract pharmacies. *See id.* § 2(2). AbbVie is left only to guess at what that means. Meanwhile, the Attorney General wields boundless discretion to arbitrarily impose civil and even *criminal* sanctions on manufacturers for violating that impenetrable provision. *Id.* § 5(B); Okla. Stat. tit. 36, § 117. Such an arrangement hardly comports with due process.

18. AbbVie seeks a declaration that H.B. 2048 is unconstitutional because it is preempted by federal law, constitutes an unconstitutional taking, and is void for vagueness. AbbVie further seeks injunctive relief barring the Oklahoma Attorney General from enforcing H.B. 2048 against AbbVie.

#### **PARTIES TO THE ACTION**

19. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world’s most complex and serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need. AbbVie’s headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HHS’s Health Resources and Services Administration (“HRSA”).<sup>1</sup>

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<sup>1</sup> On February 11, 2025, President Trump issued Executive Order 14210, titled “Implementing the President’s ‘Department of Government Efficiency’ Workforce Optimization Initiative. *See* 90 Fed. Reg. 9669 (Feb. 11, 2025). On March 27, 2025,

20. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

21. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

22. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

23. Pharmacyclics LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

24. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

25. Defendant Gentner Drummond is the Attorney General of the State of Oklahoma. The Attorney General is responsible for prosecuting civil and criminal actions on behalf of the State. Okla. Stat. tit. 74, § 18b(A)(1). He is also specifically empowered

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HHS announced it intended to restructure, including by creating an Administration for a Healthy America (or “AHA”) which will have authority over, among other sub-agencies, HRSA. *See* Dep’t of Health & Human Servs., *HHS Announces Transformation to Make America Healthy Again* (March 27, 2025), <https://www.hhs.gov/press-room/hhs-restructuring-doge.html>.

to enforce H.B. 2048 against manufacturers and impose penalties for violations. H.B. 2048 § 5(B). And the Attorney General is authorized to “establish rules and regulations” interpreting H.B. 2048’s provisions about manufacturers. *Id.* This suit is brought against the Attorney General solely in his official capacity.

### **JURISDICTION AND VENUE**

26. AbbVie’s causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution.

27. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 1332, and 28 U.S.C. § 1343(a)(3).

28. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Court’s inherent equitable powers, including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908).

29. Venue is proper in this District under 28 U.S.C. § 1391(b) because this action challenges an Oklahoma law that is applicable to AbbVie’s sale and distribution of drugs within this District. AbbVie sells and distributes drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because Defendant maintains an office within this District through which he would enforce the challenged law.

## GENERAL ALLEGATIONS

### A. The 340B Drug Pricing Program

30. This case concerns section 340B of the federal Public Health Service Act, which created the federal “340B program” as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

31. The purpose of the federal 340B program is to “reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve” by creating “a low-cost source of pharmaceutical medication for the indigent patients themselves.” Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

32. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992). Through the Veterans Health Care Act, Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers’ previous voluntary support into a federal mandate.

33. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must “offer” its covered outpatient drugs “for purchase” at deeply discounted prices to eligible “covered entities”—disproportionate

share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1).

34. The statute expressly limits participation in the 340B program to “covered entities.” *See id.* § 256b(a)(4). The statute defines “covered entities” to include only organizations and service providers that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children’s hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id.* For-profit commercial pharmacies are not included in the statutory list of “covered entities.” *Id.* Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers’ drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) (“It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.”), *aff’d sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

35. The discounted 340B price for each of the manufacturers’ drugs is calculated by subtracting the drug’s Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. 42 U.S.C. §§ 256b(a)(1)-(2) & (b). The resulting prices, called the 340B “ceiling prices,” are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the

average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

36. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement (“PPA”). That agreement is drafted by HHS. It has “no negotiable terms,” and it “incorporate[s] the statutory obligations and record[s] the manufacturers’ agreement to abide by them.” *Astra*, 563 U.S. at 117-18.

37. The PPA imposes no obligation on participating manufacturers to make ***unconditional*** sales to covered entities. Additionally, the PPA neither requires manufacturers to sell discounted drugs to contract pharmacies nor to facilitate the transfer of their discounted drugs to contract pharmacies. Nor does it grant covered entities any right to obtain unfettered access to manufacturers’ drugs at discounted prices through contract pharmacies.

38. Both the PPA and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or profiting from the sale of manufacturers’ drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers’ deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the

covered entity through the federal 340B program at discounted prices, pocketing the difference (the “spread”) for their own financial benefit.

39. In recent years, commercial contract pharmacies have earned annually over \$3.3 **billion** in “spread.” See Eric Percher et al., Nephron Rsch. LLC, *The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption*, at 3, 30-31 (2020) (concluding that \$3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

40. These abuses of the federal 340B program violate the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus between the federal drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers’ drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

41. The federal statute expressly forbids “diversion” by prohibiting covered entities from selling or otherwise transferring any manufacturer’s discounted drugs “to a person who is not a patient of the entity.” 42 U.S.C. § 256b(a)(5)(B) (“With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.”).

42. The statute also prohibits covered entities from receiving or causing “duplicate discounts or rebates.” They may not obtain a 340B discount and cause a

Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id.* § 256b(a)(5)(A).

43. H.B. 2048 unconstitutionally compels AbbVie to make sales under conditions it would not agree to, thereby enabling and perpetuating the very abuses federal law forbids.

44. The 340B statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program’s integrity by “provid[ing] for improvements in compliance by covered entities ... in order to prevent diversion” and violations of the statute’s duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

45. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution (“ADR”) process. *See id.* §§ 256b(d)(1)(B)(v), (d)(3). Notably, HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process. *See* 89 Fed. Reg. 28643 (Apr. 19, 2024). The final rule established a comprehensive scheme to resolve disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a “340B ADR Panel” within HRSA is tasked with resolving not only disputes about drug prices but also “claims that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price”—the exact issue H.B. 2048 seeks to address. *See* 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) (“A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that facilitate the sale or distribution of its drugs to covered entities.”); 89 Fed. Reg. at 28649

(“HHS agrees and has modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price.”); *id.* at 28644 (“[T]he 340B Program is related to drug pricing and drug distribution.”).

46. The statute entrusts enforcement of the 340B statute *exclusively* to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. §§ 256b(a)(5)(C)-(D), (d)(1)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities “would undermine [HHS’s] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.” *Astra*, 563 U.S. at 119-20.

47. Failure to comply with the statutory requirements under the 340B program may result in termination of the PPA (and the manufacturer’s ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See* 42 U.S.C. §§ 256b(a)(5)(D), (d)(1)(B)(vi), (d)(2)(B)(v), (d)(3)(A).

## **B. The Growth in Contract Pharmacy Arrangements**

48. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities *that lacked an in-house pharmacy* from entering into a contractual relationship with a *single* outside pharmacy to dispense covered outpatient drugs to the covered entity’s patients. 61 Fed. Reg. 43549 (Aug. 23, 1996). The guidance made clear that it “create[d] no new law and create[d] no new rights or duties.” *Id.* at 43550.

49. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

50. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of “contract pharmacies,” even if the covered entity had an in-house pharmacy of its own. 75 Fed. Reg. 10272 (Mar. 5, 2010).

51. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10273 (“This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law.”). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities’ use of contract pharmacies.

52. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 12,000% between 2010 and 2024. *See* Elanor Blalock, *For-Profit Pharmacy Participation in the 340B Program: 2024 Update*, BRG (Jan. 2025) (“BRG Report”),

<https://tinyurl.com/2k8daabf>. As of 2023, over 33,000 pharmacy locations—“more than half of the entire U.S. pharmacy industry”—acted as 340B contract pharmacies, up from fewer than 1,300 pharmacy locations in 2010. See U.S. Senate Comm. on Health, Educ., Labor & Pensions, 119th Cong., *Congress Must Act To Bring Needed Reforms To The 340B Drug Pricing Program* 3 (Apr. 2025) (“Cassidy Report”), <https://tinyurl.com/44c6w2en>. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B-discounted drugs. For example, in 2009 sales of 340B-priced drugs totaled just \$4.2 billion, but by 2023 they had increased by more than 30-fold to \$124 billion. See Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer Cntr. For Health Pol’y & Econ. 5 (Oct. 2021) (“Mulligan”), <https://tinyurl.com/3a5h2zex>; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to \$124B in 2023*, IQVIA (2024), <https://tinyurl.com/ywkdbbjju>.

53. Similarly, the number of covered entities participating in the program jumped from around 15,000 in 2010 to more than 50,000 by 2020. See Mulligan, *supra*, at 4; U.S. Gov’t Accountability Off., *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 23 (2019), <https://www.gao.gov/assets/d20108.pdf> (“Given the weaknesses in HRSA’s oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible.”).

54. Nor does the program's explosive growth correlate with an increase in indigent patients, or improvements in care. Indeed, since 2010, the percentage of uninsured patients in the United States has fallen by nearly 38%. *See* Kenneth Finegold et al., U.S. Dep't of Health & Hum. Servs., Off. of the Assistant Sec'y for Planning & Evaluation, Trends in the U.S. Uninsured Population, 2010-2020, Issue Brief No. HP-2021-02, at 2 (Feb. 11, 2021), <https://tinyurl.com/4rf9cm8t>.

55. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies are not "agents" of the covered entities; they are merely business partners. Indeed, large contract pharmacies like CVS and Walgreens charge "complex fees for pharmacy and administrative services to covered entities" that increase year over year. Cassidy Report, *supra*, at 18. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

56. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

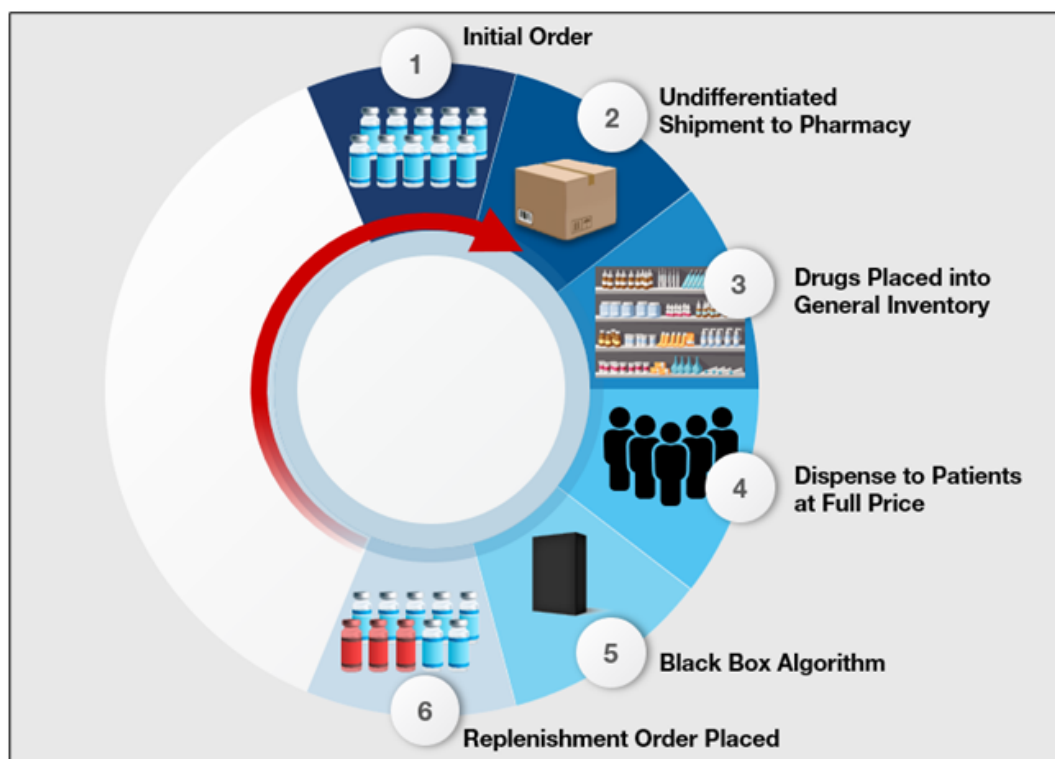
57. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy, and

when filling prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B-purchased inventory.

58. Most contract pharmacies, however, use what is known as the “replenishment” model. The replenishment model is, as covered entities self-describe it, “an accounting mechanism” by which they retroactively match discounts for the pharmacy with previously (full price) dispensing events to customers. *See* Summ. J. Hr’g Tr. at 59-60, *AbbVie Inc. v. Murrill*, No. 6:23-CV-01307-RRS-CBW (“*Murrill*”), ECF No. 84 (W.D. La. June 6, 2024) (Ron Connelly, counsel for the Louisiana Primary Care Association); 61 Fed. Reg. 43549, 43555 (Aug. 23, 1996). In practice, the replenishment model permits the “transfer” of 340B-priced drugs to contract pharmacies with the full knowledge that those drugs will be sold to any customer who comes in the door, whether 340B-eligible or not.

59. Under the replenishment model, no 340B-purchased drugs are kept in stock at the contract pharmacy. Instead, “the pharmacy has an initial stock of drugs” obtained through ordinary commercial purchases at the non-340B price (Figure 1, step 1). *See Murrill*, Summ. J. Hr’g Tr. at 60 (Ron Connelly, counsel for the Louisiana Primary Care Association). Initially, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. As explained below, the pharmacy determines which previous dispenses were 340B eligible and once sufficient eligible dispenses for a particular drug accumulate, the covered entity orders additional quantities of that drug at the federal 340B price (Figure 1, step 6). The covered entity directs AbbVie to transfer those drugs to the contract pharmacy to “replenish” the non-340B-priced drugs dispensed by the contract pharmacy

on the covered entity's behalf (Figure 1, step 2). *See* Decl. of RADM Krista M. Pedley, Dir., Off. of Pharmacy Affs., HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD, ECF No. 125-2 ¶¶ 3-11 (S.D. Ind. June 25, 2021). Sometimes the contract pharmacy actually places the order on behalf of the covered entity for more drugs at the federal 340B price.



**Figure 1.** Replenishment Model Step-By-Step.

60. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs are “placed on the shelf, become[] ‘neutral inventory,’ and may be dispensed to any subsequent patient” (Figure 1, step 3). *See id.* ¶ 11.

61. In other words, under the replenishment model, contract pharmacies do not keep a separate inventory of 340B-priced drugs but instead dispense drugs to both 340B

and non-340B patients alike out of their general inventories. Nor do most contract pharmacies attempt to determine prior to or at the point of sale whether the patient is eligible for a 340B discounted drug. In almost all instances, contract pharmacies dispense the 340B-priced drugs to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient (Figure 1, step 4). The pharmacy or a third-party administrator (“TPA”) carries out a 340B determination at the back end, well after a drug has been dispensed (and likely consumed) by the patient. This determination is made using a black box algorithm (unknown by AbbVie) based on the contract pharmacy’s own criteria, without any involvement from the covered entities (Figure 1, step 5). If those criteria are designed correctly, the post-sale determination may be able to calculate how many 340B-priced drugs AbbVie must sell. But in reality, the contract pharmacies’ criteria often include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but that are included under a “once-a-patient-always-a-patient” approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. As the D.C. Circuit observed, “[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.” *Novartis*, 102 F.4th at 457-58.

62. Aside from diversion created by the pharmacies and covered entities’ use of their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices, the replenishment model encourages diversion by allowing

covered entities to transfer federally discounted drugs to pharmacies, who are not “a patient of the entity.” *See* 42 U.S.C. § 256b(a)(5)(B).

63. Although HRSA interpreted the federal 340B statute to allow the use of pharmacies, it did so because “[w]e believe that the relationship between the covered entity and the contract pharmacy is one of agency.” 61 Fed. Reg. 43549, 43554 (Aug. 23, 1996). Additionally, HRSA noted that the covered entity purchases the drugs, and must retain title and responsibility for them even after directing shipment to the contract pharmacy. *Id.* at 43553. However, in practice, covered entities do not retain title to the drugs.

64. As explained above, contract pharmacies (typically through a TPA) instruct covered entities to place orders—sometimes even placing the order itself, without going through a covered entity—of additional quantities of drugs at the discounted 340B price to “replenish” the general inventories that they will use to supply non-340B-eligible sales. Significantly, as a result of such replenishment, even though the drugs are purchased by or on behalf of covered entities, contract pharmacies effectively take title to the drugs. At no point in time does a covered entity take title to the drugs under this model. *See Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Contract Pharmacies*, 340B Report (June 13, 2024), <https://tinyurl.com/bdmx88wu> (according to a covered entity spokesperson, “in order for the replenishment model to function, ‘the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory.’”). AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity.

65. In practice, therefore, covered entities and contract pharmacies share in the “spread” generated by selling the drugs at higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients’ insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

66. By dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress’s intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated approximately \$64 billion in estimated gross profits from the purchase of manufacturers’ drugs at mandated 340B prices. *See* BRG Report, *supra*, at 7. And a recent report from the U.S. Senate Committee on Health, Education, Labor & Pensions found that a covered entity in Virginia generated \$276.5 million in 340B savings and revenue from September 2018 through September 2023, while another covered entity in Ohio accrued \$933.7 million in 340B savings and revenue from April 2020 through June 2023. Cassidy Report, *supra*, at 6.

67. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers’ discounted drugs will be dispensed to individuals who are not “patients” of the covered entity. As HHS has found, contract pharmacy arrangements “create complications in preventing diversion” (for example,

contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS Office of Inspector General, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1 (2014) (“HHS Report”), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

68. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. See U.S. Gov’t Accountability Off., *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 44 (June 2018), <https://www.gao.gov/assets/d18480.pdf> (noting that approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies); *id.* at 35, 43-44 (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies, and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

69. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers’ drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. See HHS Report, *supra*, at 2 (finding that “some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies”); Cassidy Report, *supra*, at 9 (explaining that the covered entities under investigation “do not pass 340B discounts

directly to their patients and differ on how patients receive discounts on their 340B drugs”); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020), <https://tinyurl.com/yxehpc7v> (explaining that “almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals,” while patients “don’t benefit,” even though manufacturers have “practically given the product away”); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA 12 (Sept. 27, 2022), <https://tinyurl.com/2wdtuh52> (“The 340B Drug Discount Program as it exists today is a complex system of arbitrage ... in which most vulnerable patients at contract pharmacies do not get drug discounts.”); Lin JK et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum 2 (June 17, 2022) (finding that contract pharmacy growth from 2011 to 2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

70. For example, the North Carolina Department of the State Treasurer published a recent report explaining that “some hospitals are using the 340B program to enrich themselves rather than to serve vulnerable communities,” and that the hospitals “expanded into wealthier neighborhoods with a higher percentage of insured individuals who could pay more for the drugs.” Dale R. Folwell, N.C. Dep’t of State Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*, N.C. State Health

Plan, at 3, <https://tinyurl.com/4cy8an69>. This State is no different: nearly half of Oklahoma’s contract pharmacies are located in affluent neighborhoods. *See* Pioneer Institute Public Policy Research, *340B In Oklahoma* (2024), <https://tinyurl.com/4wts46j9>.

71. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals’ uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program, 7-8 (Oct. 30, 2020), <https://tinyurl.com/4s5ptxxy>; Adam J. Fein, *EXCLUSIVE: 340B Program Purchases Reach \$24.2 Billion—7%+ of the Pharma Market—As Hospitals’ Charity Care Flatlines, Drug Channels* (May 14, 2019), <https://tinyurl.com/4z8dmjsv>.

72. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable large scale arbitrage and damage the very communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022), <https://tinyurl.com/3sbxuswa> (describing how one 340B hospital “has been slashing services at Richmond Community while investing in the city’s wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses”); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn’t Mean Markdowns for Patients*, Wall. St. J. (Dec. 22, 2022), <https://tinyurl.com/yc2uc6yp> (“The

data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid” which “raise questions about the program’s growth and purpose.”).

73. A recent New York Times investigation into Apexus, the government contractor managing 340B drug pricing, exposed systemic price manipulation, lack of oversight, and financial exploitation within contract pharmacy arrangements—allowing for significant financial abuse at the expense of the communities the program was meant to protect. Apexus, which is responsible for negotiating better prices and access to medications, has a direct financial incentive to expand the program and maximize hospital profits. Because Apexus “is allowed to collect a fee for almost every drug sold under the program,” it has actively developed strategies to drive 340B sales and increase covered entity revenue. These strategies include training covered entities on how to maximize 340B revenue; operating a “purchasing optimization team” advising hospitals on which drugs to generate the highest margins; and running a certification program teaching hospitals how to capture more patients and prescriptions under 340B. These tactics have prioritized profit generation over patient benefit, increasing Apexus’s and covered entities’ financial gains at the expense of patients, insurers, and manufacturers. Hospitals face no restrictions on which outpatient prescriptions they classify as 340B, allowing them to mine patient records from as far back as 36 months to claim additional patients under the program—even if those patients never directly benefit from the discounts. In some cases, hospitals have passed inflated drug costs onto patients instead of sharing the savings. *See*

Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 15, 2025), <https://tinyurl.com/33ftpfd>.

74. Congress has also expressed concern over growing abuses in the 340B program. On April 24, 2025, the Majority Staff of the Senate Health, Education, Labor & Relations (“HELP”) Committee, chaired by Senator Cassidy, released a report titled “Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program,”—the culmination of a nearly two-year investigation into contract pharmacy arrangements and other 340B-related issues. In its findings, the Senate HELP Committee determined that not only have contract pharmacies grown by sheer numbers, but major commercial pharmacy chains like CVS, Walgreens, Express Scripts, OptumRx, and Walmart, account for 75% of all contract pharmacy relationships. *See Cassidy Report, supra*, at 3.

75. As part of the Senate HELP Committee’s investigation, several covered entities expressly told Congress that they do not pass on discounts to patients, and do not specifically account for 340B revenue in their budgets. *See id.* at 10. And large commercial pharmacy chains like CVS and Walgreens disclosed that they collect significant fees associated with 340B dispensing. For example, for patients with third-party insurance, CVS collects between \$35 and \$85 per brand-name drug dispensing event depending on the days-supply of the prescription dispensed. *Id.* at 18. CVS reported to the Committee that in 2023 it made \$382 million in 340B-related dispensing fees and “annual gross and net revenues generated from the 340B program.” *Id.* at app. 106.

76. While the replenishment model contributes to the abuses described above—issues manufacturers are rightfully trying to address—H.B. 2048 goes further: it mandates

that manufacturers sell or transfer discounted drugs on terms Congress never required and that manufacturers never agreed to. The injuries manufacturers face under H.B. 2048 do not stem from the 340B program itself or even from the replenishment model specifically, but from the state's attempt to override federal law and impose *state* requirements on AbbVie's participation in a *federal* program. Even if the replenishment model were eliminated entirely, H.B. 2048 would still compel manufacturers to transfer property under conditions they oppose, stripping them of their federally acknowledged ability to impose reasonable limitations on their 340B offers. In doing so, H.B. 2048 not only conflicts with federal law—it also effects a taking. The statute forces manufacturers to sell valuable property at below-market rates, to third parties, with no room to impose conditions or decline a sale. That is AbbVie's injury. The abuses simply underscore the stakes.

### **C. Manufacturers' Response to HRSA's Overreach**

77. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers provide their discounted 340B-priced drugs to an unlimited number of commercial pharmacies.

78. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B-discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing covered entities.

79. As 340B abuse continued to grow, with covered entities seeking the provision of 340B-priced drugs to an excessive number of for-profit pharmacies—sometimes located more than 100 miles from the covered entity's location—AbbVie updated its policy to place reasonable limits around provision to contract pharmacies.

Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy now is to only take orders for the in-house pharmacy. However, if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, AbbVie will take orders for one designated contract pharmacy, provided that the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site, and the covered entity submits limited claims data on 340B utilization for that pharmacy location. In addition, Grantee Covered Entities may use an unlimited number of contract pharmacies as long as the Grantee registers with 340B ESP<sup>TM</sup>, a web-based platform made available to covered entities at no cost, and submits claims data.<sup>2</sup> *See* Letter from E. Scheidler to 340B Covered Entities (Feb. 27, 2025), <https://tinyurl.com/mr2rac4u>.

80. In implementing its initiatives, AbbVie has confirmed that it will continue to offer “each covered entity” the ability to “purchase” its covered outpatient drugs “at or below the applicable ceiling” price set by statute. *See* 42 U.S.C. § 256b(a)(1). AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

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<sup>2</sup> “Claims data,” as used in the administration of the 340B program, refers to prescription-level information necessary to determine whether a drug is subject to a 340B discount, a Medicaid rebate, or both, and whether the recipient is a patient of a covered entity.

81. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

82. AbbVie's policy is not only consistent with those upheld by the Third and D.C. Circuits but also gives covered entities and contract pharmacies more convenience at its own expense. *See Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th at 463-64.

83. AbbVie's compelled compliance is directly attributable to Oklahoma's enactment of H.B. 2048, which is set to come into effect on November 1, 2025.

#### **D. Litigation in Federal Courts**

84. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), <https://340breport.com/hrsa-says-its-340b-contract-pharmacy/>. HHS then reversed its position and attempted to impose a new obligation on manufacturers.

85. On December 30, 2020, HHS issued a final decision—labeled an “Advisory Opinion”—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* U.S. Dep't of Health & Hum. Servs., Advisory Op. No. 20-06, Contract Pharmacies Under the 340B Program,

at 1 (Dec. 30, 2020), <https://tinyurl.com/2ca6rmnm>. Various manufacturers brought suit in early 2021 to challenge this HHS decision.

86. On May 17, 2021, the government sent certain manufacturers “violation” letters purporting to enforce the 340B statute. AbbVie received a violation letter on October 17, 2022, stating that HHS had made a final determination that AbbVie’s policy violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies because “AbbVie’s actions have resulted in overcharges.” *See* U.S. Dep’t of Health & Hum. Servs., Violation Letter to AbbVie (Oct. 17, 2022), <https://tinyurl.com/47ybp3kw>.

87. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca*, 543 F. Supp. 3d 47, the previously issued violation letters were not withdrawn.

88. Many of Oklahoma’s sister states filed amicus briefs in the Third and D.C. Circuit Courts of Appeals in support of HHS, expressing disapproval of the manufacturers’ policies. *See* Brief of Amicus Curiae States, *Sanofi*, 58 F.4th 696 (3d Cir. 2023) (Nos. 21-3167 et. al), 2022 WL 1617655; Corrected Brief of Amicus Curiae States, *Novartis*, 102 F.4th 452 (D.C. Cir. 2024) (Nos. 21-5299 et al.), 2022 WL 1644996.

89. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally “chose not to” impose delivery-related obligations on manufacturers, explaining that the federal 340B statute’s plain text suggests that Congress intended “one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.” *See Sanofi*, 58 F.4th at 704.

90. The Third Circuit further found that manufacturers’ policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers’ policies, covered entities “can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy.” *Id.* at 703.

91. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

92. On May 21, 2024, the D.C. Circuit issued its own opinion endorsing the same view, holding that “section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount.” *Novartis*, 102 F.4th at 460. As a result, as long as a manufacturer’s policy “neither precludes [it] from making a bona fide ‘offer’ nor increases its contract ‘price’”—such as only “deliver[ing] section 340B drugs to a covered entity’s in-house pharmacy or to a single contract pharmacy designated by the covered entity”—the condition is legitimate and may be enforced without running afoul of section 340B. *Id.* at 463-64.

93. In the face of those federal decisions, several states enacted their own laws trying to achieve what HHS could not. Those state laws—passed in Arkansas, Louisiana, Maryland, Mississippi, Missouri, West Virginia, South Dakota, North Dakota, Utah, and others—try to limit manufacturers’ ability to condition the federal offer by forcing them to transfer their drugs to an unlimited number of contract pharmacies at the 340B-discounted

prices. A new round of federal litigation commenced. Manufacturers challenged the laws as unconstitutional on several grounds, and that litigation continues today.

94. Some courts have allowed the state laws to take effect. *See, e.g., PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024) (Arkansas). By contrast, the Southern District of West Virginia preliminarily enjoined West Virginia’s contract pharmacy law, holding the law unconstitutionally conflicted with section 340B. *PhRMA v. Morrissey*, 760 F. Supp. 3d 439, 451-60 (S.D. W. Va. 2024). The West Virginia court found that laws like Oklahoma’s H.B. 2048 regulate “price, not delivery.” *Id.* at 455. Under such laws, “[t]he question is only about what price the pharmacy and the covered entity will pay.” *Id.* In other words, “the system is about delivery *at a given price*, not delivery *per se*.” *Id.*

95. Other cases await decisions in district court, and multiple appeals are now pending before the U.S. Courts of Appeals for the Fourth and Fifth Circuits.

#### **E. The Oklahoma Law**

96. After federal courts concluded that the federal 340B statute grants manufacturers the freedom to adopt policies to combat contract-pharmacy 340B abuse, Oklahoma turned to its own legislature to take that freedom away.

97. In February 2025, the Oklahoma legislature introduced legislation—H.B. 2048—to limit manufacturers’ right to attach reasonable conditions to the federal 340B offer made to covered entities. The legislature passed H.B. 2048 on May 12, 2025.

98. Recognizing H.B. 2048’s serious problems, Governor Kevin Stitt vetoed the bill on May 17, 2025. In his official veto message, Governor Stitt explained that the 340B program “is in deep need of reform *at the federal level* to improve transparency.” H.B.

2048 Veto Message (May 17, 2025) (emphasis added), <https://tinyurl.com/5fsuaeh4>. He added that the President of the United States “is working to address this issue” and that it is not “the job of the [Oklahoma] legislature to insert itself into a contractual dispute and try to pick winners and losers.” *Id.*

99. Despite Governor Stitt’s objections, the Oklahoma legislature overrode his veto on May 29, 2025, thereby enacting the bill without gubernatorial approval. H.B. 2048 is set to take effect on November 1, 2025.

100. The text of H.B. 2048 makes clear that changing the terms of the federal 340B program and compelling a private wealth transfer of 340B-priced drugs from one party to another are its regulatory objects.

101. Start with its key defined terms. H.B. 2048 defines “340B drug” as “a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to [42 U.S.C. § 256b (*i.e.*, the federal 340B statute)] and is purchased by a covered entity as defined in [§ 256b(a)(4)].” H.B. 2048 § 2(1). H.B. 2048 also defines “340B entity”—another critical term—by referencing the federal 340B statute. *Id.* § 2(2). In other words, the Oklahoma statute cannot exist outside the context of the federal 340B program.

102. H.B. 2048 eliminates manufacturers’ ability to adopt policies to prevent 340B abuse or prevent the taking of their own property by entities not otherwise entitled to it: “A manufacturer shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to a 340B entity, unless such receipt is prohibited by [HHS].” H.B. 2048 § 4(A).

103. H.B. 2048 expands the pool of entities authorized by Congress to receive drugs purchased at 340B prices. It sweepingly defines “340B entity” to include “any *pharmacy* contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.” H.B. 2048 § 2(2) (emphasis added). So Oklahoma demands that manufacturers provide both covered entities and commercial contract pharmacies unfettered access to their drugs at discounted 340B prices. That is contrary to what Congress wanted. *See* 42 U.S.C. § 256b(a)(5)(B) (providing that “a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity”).

104. Then, in a broad catch-all provision, Oklahoma’s law states that “[a] manufacturer shall not interfere with a pharmacy contracted with a 340B entity.” H.B. 2048 § 4(B). The law does not define “interfere.” And, as noted above, the definition for “340B entity” already includes commercial contract pharmacies—so § 4(B) necessarily bars “interference” with unspecified third-party pharmacies who happen to have contracts (of seemingly any type) with other pharmacies. How such a provision could ever be fairly enforced is anyone’s guess.

105. Not content to stop there, Oklahoma’s law affirmatively requires “340B entities” (which, again, include contract pharmacies) to “contract with any willing pharmacy upon mutually agreeable terms within a fifteen-mile radius of the 340B entity’s location.” H.B. 2048 § 4(C). Setting aside the confusing fact that § 4(C) seemingly mandates pharmacy-to-pharmacy contracts, this provision purports to expand the federal 340B program in a way no government has tried before: Nobody—not any of the other states with illegal contract-pharmacy laws, not HHS or HRSA, and certainly not

Congress—has ever suggested that contract-pharmacy arrangements are a *mandatory* part of the 340B program. Oklahoma stands alone.

106. Perhaps recognizing that H.B. 2048 imposes vague and sometimes incomprehensible requirements, the statute authorizes the Oklahoma Attorney General to “establish rules and regulations interpreting the provisions of this act concerning any person or entity who is not a health insurer.” H.B. 2048 § 5(B).

107. The Attorney General is further empowered to enforce the law against manufacturers and impose civil fines of up to \$10,000 per violation. H.B. 2048 § 5(B). “A violation occurs each time a prohibited act is committed.” *Id.* § 5(C).

108. H.B. 2048 also imposes *criminal* liability on manufacturers who violate its provisions. The relevant H.B. 2048 provisions will be codified in Title 36 of Oklahoma’s compiled statutes—called the “Oklahoma Insurance Code.” *See* H.B. 2048 §§ 1-6; Okla. Stat. tit. 36, § 101. And the Insurance Code provides that, “[i]n addition to any other penalty which may be applicable thereto, either under this Code or otherwise, violation of any provision of this Code shall constitute a misdemeanor and shall be punishable as such where no greater penalty is provided therefor.” Okla. Stat. tit. 36, § 117. The Attorney General is empowered to prosecute such criminal laws. *See* Okla. Stat. tit. 74, § 18b(A)(1).

109. H.B. 2048 thus authorizes the Oklahoma Attorney General to use his powers to impose severe civil and criminal consequences on pharmaceutical manufacturers who fail to comply with covered entities’ (and commercial pharmacies’) demands related to the 340B program.

110. H.B. 2048 cites no source, under the 340B statute or elsewhere, that authorizes Oklahoma to add requirements to the conditions for participating in the federal 340B program, to expand the pool of entities permitted to benefit from 340B pricing, to compel the transfer of AbbVie's property at confiscatory prices for private use, or to establish an enforcement process for Oklahoma state officials to seek remedies for alleged violations of the federal 340B requirements.

111. In one section, H.B. 2048 purports to limit its own scope to avoid conflicts with federal law. It states that “[n]othing in this act is to be construed or applied to be in conflict with ... [a]pplicable federal law and related regulations.” H.B. 2048 § 6(B)(1). But there is no way to harmonize H.B. 2048 with the federal 340B statute. Federal law leaves no role for states to regulate the transfer of 340B-priced drugs to pharmacies who are not permitted as a matter of federal law to participate in the federal program or obtain access to manufacturers' drugs at discounted prices. H.B. 2048's provisions inevitably conflict with Section 340B's requirements and exclusive federal enforcement scheme.

### **STANDING**

112. AbbVie is injured by H.B. 2048 because H.B. 2048 imposes state-level requirements not mandated by Congress and that directly conflict with and frustrate the federal 340B program. H.B. 2048 overrides the discretion manufacturers retain under federal law to impose reasonable conditions on their 340B offers, and subjects AbbVie to conflicting obligations, compliance burdens, and potential enforcement actions. The law also forces AbbVie to provide its private property to another private party in a prohibited A-to-B wealth transfer. Moreover, the law subjects AbbVie to the Oklahoma Attorney

General's enforcement of H.B. 2048's requirements. Plaintiffs are signatories to 340B PPAs, and/or are successors-in-interest to executed 340B PPAs, with HRSA.

113. AbbVie's injuries are fairly traceable to H.B. 2048 because the state statute compels a private transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies—in the absence of any recognized public use or purpose and in violation of federal law. H.B. 2048 compels sales at the discounted price against AbbVie's wishes and on terms it would not agree to; in other words, in the absence of H.B. 2048, those sales or other transfers to covered entities and their contract pharmacies at the discounted price *would not occur*. The statute prohibits AbbVie from enforcing its contract pharmacy policy, which otherwise conditions the sale or transfer of 340B-discounted drugs. H.B. 2048 thus compels a transaction that would not take place but for the state's law. Put differently, the existence and enforcement of H.B. 2048 results in the difference between a sale at the discounted price occurring or not. In addition, the statute seeks to impose new state-law obligations on drug manufacturers participating in the 340B program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the PPA, contains these requirements. Moreover, H.B. 2048 purports to authorize the Oklahoma Attorney General to enforce the Act in a way that violates federal law and infringes on AbbVie's property rights.

114. A favorable ruling is likely to redress AbbVie's injuries. Enjoining the provisions of H.B. 2048 that unconstitutionally force the taking of manufacturers' private property for no public use would redress AbbVie's injuries because AbbVie's property would not be unconstitutionally taken, and AbbVie would not be exposed to state-imposed

penalties for exercising its rights under the 340B program and the Constitution. Similarly, a declaratory judgment would redress AbbVie’s injuries because AbbVie would not be exposed to enforcement actions, accumulating penalties, and criminal liability.

### **BASIS FOR INJUNCTIVE RELIEF**

115. Harm is irreparable “when the injury can[not] be adequately atoned for in money, or when the district court cannot remedy [the injury] following a final determination on the merits.” *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1250 (10th Cir. 2001) (internal quotations omitted); *see also Free The Nipple-Fort Collins v. City of Fort Collins*, 916 F.3d 792, 795 (10th Cir. 2019) (affirming district court’s issuance of preliminary injunction). Moreover, “[i]mposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury.” *Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010) (citing *Kan. Health Care Ass’n, Inc. v. Kan. Dep’t of Soc. Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994)); *see also Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (“The moratorium [on collecting rent during COVID-19 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery.”).

116. Like most courts, the Tenth Circuit “consider[s] the infringement of a constitutional right enough” to show irreparable injury—“no further showing” is required. *Free the Nipple*, 916 F.3d at 805-06. After all, “[w]hat makes an injury ‘irreparable’ is the inadequacy of, and the difficulty of calculating, a monetary remedy after a full trial.” *Id.*

(quoting *Awad v. Ziriak*, 670 F.3d 1111, 1131 (10th Cir. 2012)). “Any deprivation of any constitutional right fits that bill.” *Id.* Because H.B. 2048 violates AbbVie’s constitutional rights, AbbVie will suffer irreparable harm absent an injunction.

117. Forcing AbbVie to be subjected to state administrative enforcement proceedings that are preempted by and in conflict with federal law would impose irreparable harm on AbbVie. *See Kansas Health Care Ass’n*, 31 F.3d at 1545 (affirming grant of preliminary injunction when a state agency changed the reimbursement rate scheme for Medicaid-certified nursing homes because plaintiffs showed “that defendants did not engage in a bona fide findings process prior to implementing the current reimbursement rate and prior to making assurances” that the rate complied with the Medicaid Act).

118. Moreover, a taking occurs each and every time a drug manufacturer is required against its own volition to transfer its drugs at the 340B-discounted price to a commercial pharmacy for the private benefit of that for-profit pharmacy. Effecting an unconstitutional taking of AbbVie’s private property in a forced transfer to another private party for no recognized public use or purpose constitutes an irreparable injury. *See Free the Nipple*, 916 F.3d at 806; *see also, e.g., Laclede Gas Co. v. St. Charles County*, 713 F.3d 413, 419-20 (8th Cir. 2013) (affirming grant of preliminary injunction on takings claim).

119. Further, if H.B. 2048 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating H.B. 2048 simply by performing its federally mandated functions. A party may be irreparably injured in the face of the threatened

enforcement of a preempted law. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992); *see also Prairie*, 253 F.3d at 1250 (finding irreparable harm where the state’s “threat of continued citation” of tribe members under the state’s motor vehicle registration law impermissibly interfered with tribal self-government); *Occidental Petroleum Corp. v. Cities Serv. Co.*, 1982 WL 1376, at \*8 (W.D. Okla. Dec. 20, 1982) (“[E]nforcement of the Act would constitute an irreparable injury to Plaintiff, not only because the Act is unconstitutional, but also because it denies Plaintiff rights under federal securities laws. ... The denial of [a right conferred by a federal statute] is an irreparable loss which cannot be compensated in money damages.”); *Fish v. Kobach*, 840 F.3d 710, 754 (10th Cir. 2016) (“[W]e reject the notion that the source of an injury is a litigant’s decision not to comply with an allegedly unlawful state regime, rather than the regime itself.”).

120. If drug manufacturers such as AbbVie are required to provide their drugs to contract pharmacies, the magnitude of the economic loss is beyond the capacity of Oklahoma to compensate with damages. Discounted purchases under the program reached approximately \$66.3 billion for fiscal year 2023 in the United States. *See Health Res. & Servs. Admin., 2023 340B Covered Entity Purchases* (Oct. 2024), <https://tinyurl.com/56nzphvm>.

121. Any attempt to subsequently recover losses from Oklahoma would likely be barred by the doctrine of sovereign immunity under the Eleventh Amendment. *See Colby v. Herrick*, 849 F.3d 1273, 1276 (10th Cir. 2017). That alone renders AbbVie’s financial losses “irreparable injury” for purposes of seeking an injunction. *Edmondson*, 594 F.3d at 770-71.

122. The cost to AbbVie of complying with state laws like Oklahoma’s is substantial. AbbVie estimates that, for example, the cost of complying with similar state laws in Mississippi and Missouri last year cost AbbVie around \$33.1 million and \$35 million, respectively. Complying with Oklahoma’s law will cost AbbVie tens of millions of dollars per year (if not more). And as the number of states adopting these kinds of laws increases, so does the irreparable harm imposed.

123. As of filing, 18 other states have already passed contract-pharmacy laws akin to Oklahoma’s H.B. 2048—but with material differences among and between those state laws, complicating compliance and subjecting manufacturers to different and varying enforcement:

	AR	CO	HI	LA	MD	ME	MN	MO	MS	ND	NE	NM	OK	OR	SD	TN	UT	VT	WV
Restricts collection of claims data	–	✓	–	✓	–	✓	–	–	–	✓	✓	✓	–	✓	✓	✓	✓	✓	✓
Defines “340B entity” to include pharmacies	–	–	–	✓	–	✓	–	–	✓	✓	–	–	✓	–	–	✓	✓	–	–
Applies only to certain 340B covered entities	–	–	–	–	–	–	–	–	–	–	–	✓	–	–	–	–	–	–	–
Prohibits conditioning 340B offers on receipt of contracts	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	✓	–	–
Requires “acquisition” by a pharmacy or entity	–	✓	✓	✓	✓	✓	–	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Requires delivery to any location	–	✓	–	–	–	–	–	–	–	–	✓	–	–	–	✓	✓	✓	–	✓

Prohibits “interfering” with “eligible patients” or pharmacies	–	–	–	–	–	✓	–	–	–	✓	–	✓	✓	–	–	–	–	✓	–
Prohibits use of rebates	–	–	–	–	–	–	–	–	–	✓	–	–	–	–	–	–	–	✓	–
Restricts right to impose time limits on replenishment orders	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	✓	–	–
Applies to an “agent” or “affiliate”	–	✓	✓	–	–	✓	–	✓	–	–	✓	✓	–	–	–	✓	✓	✓	✓
Imposes criminal sanctions	–	–	✓	–	✓	–	–	–	✓	✓	–	✓	✓	–	–	✓	✓	–	–
Creates a private right of action	–	✓	✓	–	–	–	–	–	–	–	–	–	–	–	✓	✓	–	✓	–

124. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from H.B. 2048. That is, the law effects a repeated and ongoing mandatory private wealth transfer of AbbVie’s 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the U.S. Constitution. The law deprives AbbVie and other manufacturers of their federal rights under the actual terms of the 340B program. And H.B. 2048 threatens to impose significant penalties (including *criminal* liability) upon manufacturers if they do not capitulate to Oklahoma’s attempt to modify the terms of that federal program. The deprivation of constitutional rights constitutes irreparable injury for purposes of a preliminary injunction. *See, e.g., Free the Nipple*, 916

F.3d at 805-06; *Pinson v. Pacheco*, 397 F. App'x 488, 491 (10th Cir. 2010) (citing Wright & Miller, Federal Practice and Procedure § 2948.1 n.26 (2d ed. 1995)).

125. Granting injunctive relief here would not harm Oklahoma. It is well settled that states have no interest in enforcing unconstitutional laws. *See Edmondson*, 594 F.3d at 771 (affirming preliminary injunction because the state “does not have an interest in enforcing a law that is likely constitutionally infirm” and “the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law”); *Utah Licensed Beverage Ass’n v. Leavitt*, 256 F.3d 1061, 1076 (10th Cir. 2001) (finding that enjoining the enforcement of likely unconstitutional statutes “is an appropriate remedy not adverse to the public interest”). Moreover, there is no evidence that uninsured and needy patients—in Oklahoma or anywhere else—benefit from the use of contract pharmacies. Oklahoma has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

126. Granting injunctive relief would be in the public interest. The public has no legitimate interest in enforcing unconstitutional laws, particularly those that force a transfer of private property for no public use or purpose. By contrast, the public has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties. Further, the public has a strong interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs.

## FIRST CLAIM FOR RELIEF

### *Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2*

127. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

128. Under the Supremacy Clause of the Constitution, federal law is “the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2. As a result, federal statutes enacted by Congress can preempt state law. *See, e.g., Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000); *Kidneigh v. Unum Life Ins. Co. of Am.*, 345 F.3d 1182, 1185 (10th Cir. 2003).

129. Preemption can take multiple forms: “Federal statutes can preempt state statutes either by an express statement of preemption or by implication.” *Tarrant Reg’l Water Dist. v. Herrmann*, 656 F.3d 1222, 1241 (10th Cir. 2011).

130. One type of implied preemption is field preemption, which occurs where “Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law.” *Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150, 163 (2016). Field preemption occurs where Congress intends “to foreclose any state regulation in the area, even if it is parallel to federal standards.” *Arizona v. United States*, 567 U.S. 387, 401 (2012).

131. Every element of the federal 340B program—from eligibility and pricing to compliance and enforcement—is governed by federal law. “Price regulation is exclusively

controlled by the federal statute, and state enforcement of it would necessarily intrude on the federal scheme.” *Morrissey*, 760 F. Supp. 3d at 458 (internal citation omitted).

132. H.B. 2048 directly intrudes on the federal 340B scheme. Oklahoma’s law bars manufacturers from denying, restricting, prohibiting, or interfering with “the acquisition of a 340B drug by, or delivery of a 340B drug to” contract pharmacies, and the term “340B drug” is defined by reference to the 340B ceiling price established by federal law. H.B. 2048 §§ 2(1), 4(A). Thus, the Oklahoma law prohibits manufacturers from conditioning their 340B offers by declining to transfer their drugs to contract pharmacies *at a particular price*. See *Morrissey*, 750 F. Supp. 3d at 455-56. Manufacturers violate laws like H.B. 2048 “not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies.” *Id.* That the state law defines the drugs in issue as “340B drug[s]” confirms that H.B. 2048 is a price regulation: “**Price** is what distinguishes between an ‘ordinary drug’ and a 340B Program drug—a fact that seems to be reflected in the [Oklahoma] statute itself.” *Id.* (emphasis added).

133. Indeed, H.B. 2048 *expressly* regulates 340B drug pricing. The law defines “340B drug” to mean a drug that, among other things, is “subject to any offer for *reduced prices* by a manufacturer pursuant to [the 340B program].” H.B. 2048 § 2(1) (emphasis added). And the definition of “340B entity” is likewise pegged to “the 340B *drug discount* program.” *Id.* § 2(2) (emphasis added).

134. H.B. 2048 was enacted in response to manufacturers’ policies, which (according to HRSA and HHS) result in overcharges. But the federal statute does not

authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program. *See Arizona*, 567 U.S. at 401 (holding that where Congress has occupied the field, state laws that impose additional obligations are preempted).

135. The federal 340B statute carefully prescribes who may access 340B discounts, when, and under what conditions—including compliance with federal anti-diversion and duplicate discount requirements. The federal statute governs how prices and discounts are calculated and what obligations manufacturers must follow, requiring them to offer 340B pricing *only* to covered entities—not third parties. *See* 42 U.S.C. § 256b(a)(1).

136. It is foundational constitutional law that States may not regulate Congress's creations. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819). A state law may not change the conditions for participation in the federal Medicare and Medicaid programs. Any attempt by Oklahoma to regulate in this area impermissibly changes the requirements for participating in federal healthcare programs and nullifies the “natural effect” of federal law. *Crosby*, 530 U.S. at 372-73.

137. Another type of implied preemption is conflict preemption. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law or where “the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* (quoting *Hines v.*

*Davidowitz*, 312 U.S. 52, 67 (1941)) (alterations omitted). Oklahoma’s H.B. 2048 conflicts with or otherwise obstructs Congress’s 340B program in multiple ways.

138. H.B. 2048 effectively expands the number of entities entitled to receive 340B-discounted prices and attempts to force manufacturers to transfer their drugs to third parties—specifically, commercial pharmacies—who are not covered entities. This state regulation directly conflicts with the federal 340B statute, which authorizes discounts only to covered entities and leaves manufacturers free to impose reasonable conditions on those offers. Indeed, Congress specifically defined which entities qualify for 340B discounts and intentionally chose not to mandate manufacturer participation in contract-pharmacy arrangements. *See AstraZeneca*, 543 F. Supp. 3d at 60.

139. Oklahoma has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies that do not qualify as covered entities under the federal program.

140. The carefully delineated obligation for manufacturers to “offer” 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer’s participation in federal healthcare programs. *See* 42 U.S.C. § 256b(a)(1). To the extent that Oklahoma seeks to impose, through H.B. 2048, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law.

141. H.B. 2048’s catch-all provision prohibiting “interfere[nce]” with contract pharmacies (and pharmacies contracted to contract pharmacies) tees up other conflicts, too. *See* H.B. 2048 § 4(B). For example, if § 4(B) restricts manufacturers from demanding

claims data from covered entities, it conflicts with federal law.<sup>3</sup> The federal 340B program contemplates that manufacturers can request claims data: Before accessing the federal ADR system (the exclusive means for enforcing 340B violations), manufacturers must first “conduct an audit.” 42 U.S.C. § 256b(d)(3)(B)(iv). And before conducting an audit, the manufacturer must have “reasonable cause” to suspect a violation—which requires access to claims data. *See* 61 Fed. Reg. 65406, 65409-10 (Dec. 12, 1996) (allowing audits only when the manufacturer already “has documentation,” including “sufficient facts and evidence,” indicating that there is “reasonable cause” to believe the covered entity violated section 340B). So, to the extent that it obstructs manufacturers like AbbVie from requiring claims data or otherwise seeking clarity from covered entities, Oklahoma effectively forecloses manufacturers’ only avenues to pursue audits or claims against covered entities for violations of the 340B program’s requirements. That is why *Morrisey* found that a claims data provision in a West Virginia law directly conflicted with federal law and was thus preempted. *See Morrisey*, 760 F. Supp. 3d at 451-53.

142. Further, the replenishment model results in diversion, which the federal statute forbids. *See* 42 U.S.C. § 256b(a)(5)(B). Thus, H.B. 2048 is preempted because it expressly or impliedly protects the use of the replenishment model, a practice clearly in conflict with Congress’s mandates.

143. H.B. 2048’s contract-pharmacy obligations pose a uniquely stark conflict with the federal 340B program. Oklahoma does not merely force manufacturers to

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<sup>3</sup> As discussed below, this provision is so vaguely worded that it is impossible to know what it actually prohibits. That vagueness is itself a constitutional violation.

acquiesce to covered entities who *choose* to abuse the 340B system with contract pharmacies. That alone would conflict with federal law, but Oklahoma goes even further by also affirmatively *requiring* covered entities (and, bizarrely, contract pharmacies) to contract with all willing pharmacies within a 15-mile radius. H.B. 2048 § 4(C). No other state—not even HHS or HRSA—has taken such a brazen position and enshrined commercial pharmacies’ ability to benefit from 340B discounts as a mandatory part of the 340B program. Not content to facilitate covered entities’ and commercial pharmacies’ abuse of the federal 340B system, Oklahoma’s law actually requires it.

144. Oklahoma’s law also conflicts with the federal program by installing a parallel enforcement regime. H.B. 2048 empowers the Oklahoma Attorney General to enforce the law’s provisions against manufacturers and to punish violators with draconian state-law civil and criminal penalties. H.B. 2048 § 5(B); Okla. Stat. tit. 36, § 117. Thus, H.B. 2048 purports to grant substantive authority to Oklahoma state officials over the 340B program’s administration and enforcement, despite and in conflict with the comprehensive compliance and enforcement regime Congress provided and made exclusive. Congress chose to make “HHS administrator of both the Medicaid Rebate Program and 340B Program.” *Astra*, 563 U.S. at 120. State enforcement “would undermine the agency’s efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.” *Id.*

145. Relatedly, H.B. 2048 unlawfully purports to authorize the Oklahoma Attorney General to “establish rules and regulations” concerning the duties, rights, and obligations of manufacturers participating in the 340B program. *See* H.B. 2048 § 5(B).

But Congress left no room for states to delegate 340B rulemaking authority to state officials. Congress plainly delegated such authority exclusively to the Secretary of HHS. *See, e.g.*, 42 U.S.C. § 256b(d)(1)(A) (directing “the Secretary” to establish manufacturer-compliance regime “in order to prevent overcharges” and other 340B “violations”); *id.* § 256b(d)(3)(A) (providing that “the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims” by covered entities and manufacturers); *accord Astra*, 563 U.S. at 120-22 (stressing Congress’s desire for centralized federal authority in implementing the 340B program). By throwing another rulemaking entity into the mix, Oklahoma obstructs Congress’s wishes.

146. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), but it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C. §§ 256b(d)(1)-(3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in “overcharging.” *See id.* Oklahoma’s attempt to install an alternative compliance and enforcement regime, with different regulators and distinct penalties (including *criminal* penalties), is preempted because it conflicts with the procedures detailed in the 340B statute and any lawfully promulgated federal rules implementing the statute.

147. Finally, the growing patchwork of divergent state laws exacerbates the constitutional and compliance problems. The difficulty of complying with varying state regulatory frameworks only increases as more states pass new and different laws relating to the 340B program. As of filing, 18 states have passed contract pharmacy laws akin to H.B. 2048. State laws such as those passed by Utah, Maryland, West Virginia, Mississippi, Minnesota, Missouri, Arkansas, Kansas, Louisiana, New Mexico, Nebraska, South Dakota, and North Dakota, have material differences among and between themselves, complicating compliance by manufacturers and subjecting manufacturers to different and varying enforcement. Contrast, for example, W. Va. Code § 60A-8-6a(b) (extending similar prohibitions to an “agent, or affiliate” of a manufacturer); La. Rev. Stat. § 40:2884(B) (prohibiting a manufacturer from “interfere[ing] with a pharmacy contracted with a 340B entity”); N.M. H.B. 78, § 1(A)(4), 57th Leg., 1st Sess. (2025) (covering only entities “receiv[ing] federal grant funding”); and Neb. L.B. 168, § 3(1), 109th Leg., 1st Sess. (2025) (compelling delivery to “any location” authorized by a covered entity). Some states, like Tennessee, prohibit requiring the submission of claims data, while others do not. *Compare* Md. Health Occupations Code § 12-6C-09.1 (prohibiting restrictions on “delivery” or “acquisition” of “340B drugs”), *with* Tenn. S.B. 1414, § 47-18-136(a)(1), 114th Gen. Assembly (2025) (restricting the collection of “any health information, claims or utilization data, purchasing data, payment data, or other data”). Some states, like Utah, impose criminal penalties for failure to comply, while others do not. *Compare* Mo. Rev. Stat. §§ 407.095, 407.100, 407.110 (allowing for civil penalties), *with* Utah Code Ann. § 31A-2-308(9) (making violations of the statute a Class B misdemeanor).

148. As these laws continue to accrete, administration of the 340B program and compliance with a patchwork of state laws may become untenable, with potential catastrophic effects for the nationwide prescription drug industry. *See* Adam J. Fein, *EXCLUSIVE: The 340B Program Soared to \$38 Billion in 2020—Up 27% vs. 2019*, Drug Channels (June 16, 2021), <https://tinyurl.com/4jdjhh7u> (analyzing HRSA data to find the 340B program accounted for “16% of ... total U.S. gross sales of brand-name drugs at list prices” in 2020).

149. Importantly, the injury here flows *not* from the federal program itself, but from Oklahoma’s attempt to override and distort it. H.B. 2048 does not merely interact with the 340B statute—it imposes new obligations that conflict with the structure Congress created. Here, AbbVie does not challenge Congress’s design or dispute the requirements imposed under federal law. Rather, it challenges Oklahoma’s effort to rewrite those requirements by transforming a conditional federal offer into a mandatory, state-enforced sale on terms the federal statute does not require (and which may in fact even *violate* the federal statute), and—depending on how H.B. 2048’s vague provisions are enforced—by effectively foreclosing AbbVie’s ability to access the federal enforcement scheme. Oklahoma’s law does not fill a gap: It tears through the fabric of the federal scheme Congress designed to be uniform, voluntary, and within the exclusive federal enforcement authority of HHS.

## SECOND CLAIM FOR RELIEF

### *Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, U.S. Const. amend. V, cl. 4*

150. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

151. The Takings Clause of the Fifth Amendment provides: “[N]or shall private property be taken for public use, without just compensation.” U.S. Const. amend. V; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226, 234-35 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

152. The Takings Clause extends to both real and personal property. *Horne*, 576 U.S. at 358. It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

153. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo*, 545 U.S. at 477 (explaining that “the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation”). Such private takings are always unconstitutional, since “[n]o amount of compensation can authorize such action.” *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *see also*

*Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (“It is against all reason and justice” to allow government to “take[] property from A. and give[] it to B.”).

154. “Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). Statutes or regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

155. Oklahoma’s H.B. 2048 appropriates AbbVie’s property rights in its drugs for the private benefit of for-profit, commercial pharmacies. On its face, H.B. 2048 prohibits manufacturers from “deny[ing],” “restrict[ing],” “prohibit[ing],” or “otherwise interfer[ing] with” the “acquisition” of drugs at 340B-discounted prices by a “340B entity”—and “340B entity” is defined to include commercial contract pharmacies. H.B. 2048 §§ 2(1)-(2), 4(A). Oklahoma thus requires manufacturers to provide their drugs to commercial pharmacies or other private entities at below-market prices by purporting to add that as a state-law obligation attached to the federal 340B scheme. That is an impermissible *per se* violation of the Constitution’s Takings and Due Process Clauses.

156. H.B. 2048 mandates that pharmaceutical manufacturers provide drugs at below-market prices, depriving them of control over their own pricing structures and revenue. It compels sales or transfers of AbbVie’s drugs at the 340B-discounted price that, in the absence of H.B. 2048, would not occur. AbbVie’s offer is conditioned on the covered entity’s acceptance of AbbVie’s contract-pharmacy policy. Without H.B. 2048, if a covered entity counteroffered with a term requiring unlimited contract-pharmacy access,

AbbVie would simply refuse and no sale at the 340B-discounted price would take place. However, when H.B. 2048 is in force, it will operate to compel AbbVie to accept the counteroffer and complete the sale at the discounted price on terms AbbVie would not otherwise have agreed to.

157. H.B. 2048 expands the federal 340B program requirements in a way that shifts financial burdens onto manufacturers, reducing revenue and eliminating rebate offsets, without just compensation and with no justified public use.

158. H.B. 2048 is not for a public use. On information and belief, increased profits from contract-pharmacy participation do not result in increased charity care, reduced medical debt for patients, or better patient outcomes. *See* Expert Report of Amitabh Chandra, Ph.D., *AbbVie Inc. v. Skrametti*, No. 3:25-cv-00519 (M.D. Tenn. June 9, 2025), Dkt. No. 34-2.

159. AbbVie will never receive just compensation for H.B. 2048's takings. *See Knick v. Township of Scott*, 588 U.S. 180, 189–90 (2019) (holding that a Takings Clause violation occurs the instant a government takes private property “without paying for it”). Oklahoma law provides for no compensation at all.

160. In the alternative, H.B. 2048 effectuates a partial regulatory taking.

161. In *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the “character of the governmental action.”

162. H.B. 2048’s purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible because it requires the physical acquisition of AbbVie’s drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers’ reasonable investment-backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

### **THIRD CLAIM FOR RELIEF**

#### ***Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. amend. XIV***

163. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

164. The Due Process Clause of the Fourteenth Amendment provides that no state may “deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV, § 1.

165. A statute offends the Due Process Clause if it is impermissibly vague—*i.e.*, if the law “fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits” or “if it authorizes or even encourages arbitrary and discriminatory enforcement.” *Wyo. Gun Owners v. Gray*, 83 F.4th 1224, 1233 (10th Cir. 2023).

166. Courts are particularly skeptical of vague laws that, like H.B. 2048, impose criminal liability. “[T]he void-for-vagueness doctrine requires that a penal statute define

the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited, and it similarly means that criminal responsibility should not attach where one could not reasonably understand that his contemplated conduct is proscribed. Criminal statutes must be more precise than civil statutes because the consequences of vagueness are more severe.” *United States v. Lesh*, 107 F.4th 1239, 1247 (10th Cir. 2024) (internal citations and quotation marks omitted).

167. H.B. 2048’s text makes it impossible to know what it prohibits and how it might be enforced.

168. Consider the law’s “interference” provision: “A manufacturer shall not interfere with a pharmacy contracted with a 340B entity.” H.B. 2048 § 4(B). That provision is unconstitutionally vague because it does not provide manufacturers fair notice as to what is proscribed, and it invites arbitrary enforcement.

169. Oklahoma’s statute provides no guidance on what “interfere” means. “Interfere” (or “interference”) is not defined in H.B. 2048 or the Oklahoma Insurance Code. Nor is the term—as used in § 4(B)—part of a list that would otherwise provide context clues as to its meaning.

170. What is more, the “interference” provision contains no apparent scienter requirement. It does not, for example, require interference to be purposeful or intentional. So AbbVie could be civilly and/or criminally prosecuted for accidentally “interfering” (whatever that means) with a contract pharmacy. And that is bound to happen. Covered entities and contract pharmacies are fiercely resistant to making their contracts available to manufacturers or the public. That aggravates the already glaring vagueness problem

because manufacturers have no idea what terms they might potentially “interfere” with. *E.g., Galbreath v. Oklahoma City*, 568 F. App’x 534, 541 (10th Cir. 2014) (concluding that absence of scienter requirement made it more likely that law was unconstitutionally vague).

171. On top of all that, § 4(B)’s textual reach is not even limited to contract pharmacies or 340B-related contracts—it utterly fails to articulate *what* manufacturers are prohibited from “interfering” with. By its terms, the law prohibits interference “with a pharmacy contracted with a 340B entity.” H.B. 2048 § 4(B). But “340B entity” is already defined to include “any pharmacy contracted with [a] participating entity to dispense drugs purchased through the 340B drug discount program.” *Id.* § 2(2). Thus, AbbVie risks criminal sanctions by somehow “interfering” with *any* pharmacy (even a pharmacy that does not dispense 340B drugs) if that pharmacy happens to have some sort of unrelated private contractual arrangement with a different commercial pharmacy that dispenses 340B drugs. That is an indecipherable mess. It is impossible for AbbVie to operate its pharmaceutical business and interact with pharmacies without potentially stumbling over a criminal tripwire. So even if manufacturers could somehow divine what “interfere” means (they can’t), and even if manufacturers possessed perfect knowledge about the terms of 340B contracts between covered entities and contract pharmacies (they don’t), § 4(B) would *still* be unconstitutionally vague.

172. Head-scratching drafting choices render other H.B. 1048 provisions vague as well. For example, § 4(A) prohibits manufacturers from restricting “the acquisition of a 340B drug by, or delivery of a 340B drug to,” covered entities and contract pharmacies. And the definition of “340B drug” is limited to “a drug that has been subject to any offer

for reduced prices by a manufacturer pursuant to [the 340B program] *and is purchased* by a covered entity.” H.B. 2048 § 2(1) (emphasis added). So by its own terms, § 4(A) seemingly applies only in situations where covered entities have already accepted AbbVie’s 340B offer and thereby completed the purchase transaction. Yet AbbVie’s contract-pharmacy and other restrictions—the targets of Oklahoma’s ire—are built into the “offer” itself. Thus, to the extent § 4(A) has teeth, it apparently authorizes state officials to punish AbbVie for the “crime” of carrying out terms that covered entities contractually agreed to. In no way is that consistent with due process.

173. H.B. 2048 is thus unconstitutionally vague—both on its face and as applied to AbbVie’s ability to enforce its contract-pharmacy and claims-data policies. Oklahoma’s law fails to provide sufficient notice as to what conduct is prohibited, particularly in the complex and data-dependent context of 340B transactions. And it invites arbitrary enforcement. People of normal intelligence must guess at H.B. 2048’s meaning and may well offer vastly different yet reasonable interpretations of its scope. The ambiguity is especially concerning given the law’s criminal consequences.

### **PRAYER FOR RELIEF**

**WHEREFORE**, AbbVie prays for the following relief:

1. A declaration, order, and judgment holding H.B. 2048 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;
2. A declaration, order, and judgment declaring that H.B. 2048 effects an impermissible taking of AbbVie’s property;

3. A declaration, order, and judgment declaring that H.B. 2048 is unconstitutionally vague in violation of the Due Process Clause;
4. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to unconditionally provide 340B pricing to covered entities or contract pharmacies, or to transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies;
5. A preliminary and permanent injunction enjoining Defendant from enforcing H.B. 2048;
6. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and
7. Any other relief that this Court deems just and proper.

Dated: June 30, 2025

Respectfully submitted,

/s/ Paul DeMuro

Paul DeMuro

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